

REMARKS

Applicants' representatives would like to thank Examiner Gibson for the telephonic interview conducted on April 6, 2006. During that conference call, Applicants' representatives and Examiner Gibson discussed the Office Action, prior art and pending claims. Additionally, Examiner Gibson suggested some claim amendments to facilitate advancing the pending application.

In this paper, Applicants have cancelled claims 16 and 19 without prejudice or disclaimer and have amended claims 17, 18, 21 and 30-34. Accordingly, claims 17, 18 and 21-34 are pending in the present application. The subject matter of cancelled claim 16 has been incorporated into claim 17. Claims 21, 30 and 31 have been amended to more clearly define the weight loss attained. Claims 32-34 have been amended to clarify the particular patient. No new matter has been introduced by these amendments.

I. Drawing Objection

The Examiner objects to the drawings as failing to comply with 37 CFR 1.84(p)(5) because they include the reference character 12 not mentioned in the description but appearing in Figure 7. Applicants have obviated this objection by amending the specification to add the reference character 12 in the description in compliance with 37 CFR 1.121(b). Accordingly, Applicants request that the objection be withdrawn.

II. Rejection under 35 USC 102(b)

Claims 16, 21-24, 27-28 and 30-31 stand rejected under 35 USC 102(b) as being anticipated by Shapiro. Applicants respectfully traverse the rejection. Applicants submit that Shapiro fails to teach each and every limitation of the pending claims.

Independent claims 21, 30 and 31 each recite the limitation that the tube or passageway passes through the patient's abdominal wall. Initially, Applicants note that the stomach wall and abdominal wall are not the same thing. Although the tube in Shapiro passes through the stomach wall, Shapiro fails to teach the tube passing through the patient's abdominal wall. Rather, Shapiro teaches that "after coming out of the muscle wall of the stomach, the tube emerges on the back of the animal, under the shoulder" (Shapiro at 126). Since there is no mention or suggestion in Shapiro of the tube also passing through the patient's abdominal wall, Applicants submit that claims 21, 30 and 31 are patentable over Shapiro.

Additionally, independent claims 21, 30 and 31 each recite the limitation of attaining a clinically beneficial weight loss. In direct contrast, Shapiro fails to teach attaining weight loss. Instead, Shapiro discloses "sham feeding" to "mimic the bulimic solution of eating without calories, of eliminating weight gain while promoting oral pleasure" (Shapiro at 132). Likewise, the portion of Shapiro relied on in the Office Action describes a method for mimicking bulimia in which the process of bingeing and purging is repeated in an effort to control weight gain. One of ordinary skill in the art will appreciate that bulimics do not lose weight but rather maintain their current weight by controlling or eliminating weight gain, which is distinct from losing weight as recited in claims 21, 30 and 31. Moreover, as the Examiner suggested in the April 6th telephonic interview, Applicants have amended independent claims 21, 30 and 31 to more clearly define the degree of weight loss attained. As amended, claims 21, 30 and 31 are not anticipated by Shapiro for the reasons provided above.

Since Shapiro does not teach each and every element of independent claims 21, 30 and 31, Applicants respectfully submit that Shapiro cannot anticipate independent claims 21, 30 and 31, nor those claims dependent therefrom. Accordingly, Applicants request that the rejection be withdrawn.

III. Rejection under 35 USC 103(a)

Claims 17-19, 25, 26, 29 and 32-34 stand rejected under 35 USC 103(a) as being unpatentable over Shapiro. Applicants respectfully traverse the rejection.

Independent claim 17, as amended, recites a method comprising the step of monitoring the volume of pumped food and ending the pumping when the monitored volume exceeds present parameters within a given time. The Examiner states on page 6 of the Office Action that “Shapiro discloses a method that deals with the weight associated with a patient, so it follows that the weight loss attained would be monitored.” However, as stated above, Shapiro does not disclose a method for attaining weight loss because Shapiro relates to a method for mimicking bulimia, and it is not inherent that bulimics lose weight. Moreover, even if Shapiro was deemed to relate to weight loss, the Office Action provides no indication of why someone would be motivated to monitor the volume of pumped food and end pumping when the monitored volume exceeded preset parameters within a given time. Therefore, Applicants submit that it would not be obvious to modify Shapiro to further comprise the steps of monitoring the volume of pumped food and of ending the pumping when the monitored volume exceeds preset parameters within a given time. If the rejection is maintained, Applicants respectfully ask the Examiner to identify a reference in the field of weight loss in which the volume of pumped food was monitored, and to explain any motivation to combine.

Independent claims 32-34 are directed toward treating obesity and recite methods for treating obesity and achieving weight loss in an obese person. The Examiner states on page 8 of the Office Action that “Shapiro has correlated the models of bulimia to obesity.” Applicants submit that the only correlation between obesity and bulimia is what Shapiro discloses, i.e., both obese and bulimic persons eat too much. As stated above, Shapiro discloses a method for mimicking bulimia, and it is not inherent that bulimics lose weight. Rather, Shapiro discloses on page 132 that bulimics control weight gain, and controlling weight gain is not the same as obtaining weight loss. Moreover, Applicants have amended claims 32-34 to positively recite that the patient is obese. These claims are believed patentable based on the limitations “through an obese patient’s abdominal wall,” “allowing the obese patient to ingest food,” and “extracting the

food from the upper digestive system of the obese patient,” in view of the recent Federal Circuit decision *Perricone v. Medicis Pharmaceutical Corp.*, 77 USPQ2d 1321 (Fed. Cir. 2005). Claim 1 of the patent at issue in *Perricone* (patent No. 5,409,693) was directed to “A method for treating skin sunburn comprising topically applying to the skin sunburn a fatty acid ester of ascorbic acid” *Id.* at 1323-24. Although the prior art described topical application of the same fatty acid ester to skin, the Federal Circuit held that the general teaching of topical application in the prior art was not enough to anticipate a claim that explicitly recites topical application of the fatty acid ester to skin sunburn. *Id.* at 1328. Thus, in situations when a new use is positively recited in the steps of a method claim, “new uses of old products or processes are indeed patentable subject matter.” *Id.*

Following the same reasoning, in order to properly reject claims 32-34, the PTO has the burden of finding prior art where food was extracted from the upper digestive system of an obese patient, and where it is done through the obese patient’s abdominal wall. Since Shapiro fails to teach or suggest “extracting the food from the upper digestive system of [an] obese patient,” this limitation is not satisfied by the cited art. Applicants therefore respectfully submit that the rejection of claims 32-34 is improper for this additional reason, and respectfully request withdrawal of that rejection (or, if a new rejection is raised, identification of a reference that contains such limitations).

Accordingly, Applicants respectfully submit that independent claims 17 and 32-34 and those claims dependent therefrom are not obvious in view of Shapiro. Applicants request that the rejection be withdrawn.

The other claims in this application each depend on one of the independent claims discussed above and are therefore believed patentable for the same reasons. Since each dependent claim is also deemed to define an additional aspect of the invention, however, the individual reconsideration of the patentability of each on its own merits is respectfully requested.

IV. Provisional Double Patenting


Claims 21-34 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9, 33-39, 42, 43, 45, 49 and 54 of copending Application No. 11/191,466. Applicants agree that there is some overlapping subject matter, and agree to file an appropriate terminal disclaimer in the later-filed application at such time when overlapping subject matter is indicated as being otherwise allowable in both applications.

CONCLUSION

Applicants believe that the present application is now in condition for allowance. Favorable consideration of the application is respectfully requested. The Commissioner is authorized to charge any fees, or credit any overpayments, required in connection with this paper to Deposit Account No. 16-2500. If the Examiner has any questions, the Examiner is invited to call Applicants' representative directly at (212) 969-3000.

Respectfully submitted,

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